September 25, 2019

Substance Abuse and Mental Health Services Administration
Attention: Mitchell Berger
5600 Fishers Lane, Room 18E89C
Rockville, MD 20857

Re: Comments on Notice of Proposed Rulemaking regarding Confidentiality of Substance Use Disorder Patient Records (SAMHSA-4162-20; RIN 0930-AA30)

Dear Mr. Berger,

On behalf of the American Society of Addiction Medicine ("ASAM"), a national medical specialty society representing more than 6,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide these comments on proposed modifications to 42 CFR 2.63(a)(2) in the Substance Abuse and Mental Health Services Administration ("SAMSHSA")'s August 26, 2019 notice of proposed rulemaking (84 Fed. Reg. 44566) (this "NPRM").

To be clear, ASAM holds patients' privacy rights in the highest regard. Our decision to support changes to 42 CFR Part 2 ("Part 2") was debated at length with the implications for patients' well-being at the heart of the discussion. Ultimately, we decided that the barriers that Part 2 currently presents to coordinated, safe, and high-quality medical care cause significant harm, and thoughtful changes are necessary to mitigate this harm while protecting patients' privacy. Accordingly, ASAM continues to support regulatory and legislative changes that would more closely align Part 2 with Health Insurance Portability and Accountability Act for the purposes of health care treatment, payment, and operations. However, ASAM also continues to advocate for the need to leave in place certain, critical Part 2 prohibitions on disclosure of records outside the healthcare system.

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*The 2017 Rule, this NPRM, and Confidential Communications by Patients to Part 2 Programs*

In this NPRM, SAMHSA proposes to clarify one of the conditions under which a court may authorize disclosure of confidential communications made by a patient to a Part 2 program. Specifically, SAMHSA proposes to amend 42 CFR 2.63(a)(2), a rule governing the disclosure of certain confidential communications made by a patient to a Part 2 program when that disclosure is "in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient," by deleting the phrase "allegedly committed by the patient." SAMHSA states that the proposed change would clarify that a court may authorize disclosure of confidential communications when the disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, even if the extremely serious crime was not allegedly committed by the patient.

While SAMHSA acknowledges such phrase was recently added in SAMHSA's 2017 final rule (82 FR 6052) (the "2017 Rule"), SAMHSA states that it was done so in error. We, however, have not been able to locate any documentation supporting such a characterization. On the other hand, we also could not find any documentation that the addition of such phrase was merely a clarification of a well-accepted understanding. In fact, to the contrary, we found a written opinion by a U.S. District Court Judge in which the judge conducts a pre-2017 legal analysis involving §2.63(a)(2) and confidential communications which were potentially to be disclosed in connection with an investigation of alleged fraudulent billing by a health care provider.[i] Given this historical lack of clarity, instead of reverting back to pre-2017 language, SAMHSA should provide future certainty and clarity as to the intended scope and purpose of the rule.

Furthermore, ASAM urges SAMHSA to take this opportunity to provide clarification in a way that balances the need for appropriate federal enforcement efforts targeting "rogue doctors and pill mills" with the need to continue safeguarding, and encouraging, confidential communications between made patients and Part 2 programs. Therefore, ASAM offers the following, proposed revisions for SAMHSA's consideration:

> §2.63(a)(2) [Proposed Revisions Appearing in Bold]
>
> (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by **either (a)** the patient; **(b) the part 2 program holding the records containing the confidential communications, or (c) employees or agents of that part 2 program**, such as one which directly threatens . . . ."

At a minimum, these revisions would help guard against "fishing expeditions" to obtain information about patients' families, friends, and other associates, and other patients. Additionally, ASAM would welcome an explicit acknowledgement by SAMHSA that the legal analysis under §2.63(a)(2) is in addition to the procedures and criteria contained in §2.65 and §2.66, as applicable.

*This NPRM's Preamble Language and "Extremely Serious Crimes"*

ASAM would like to express its grave concerns about the expansive nature of new language found in this NPRM's preamble regarding the meaning of "extremely serious crimes" for purposes §2.63(a)(2). The new preamble language indicates that SAMHSA considers "opioid-related crimes" and "drug trafficking" within the meaning of "extremely serious crimes" without caveat. As currently written, such preamble language could fundamentally alter the rule's future application and scope and sharply deviate from the

historical interpretation of "extremely serious crimes." Indeed, the aforementioned U.S. District Court Judge understood the phrase "extremely serious crimes" as likely to exclude fraudulent billing, because it was difficult to conceive fraud as "sufficiently analogous" to the "violent crimes" that fall within §2.63(a)(2).[ii]

While ASAM supports efforts by the Drug Enforcement Agency (DEA) and other law enforcement agencies to hold accountable treatment providers who misuse their positions to prescribe or otherwise dispense controlled substances illegally, we would be remiss not to highlight that the medical practice of treating patients with substance use disorder is unique in certain material respects. SAMHSA's own Federal Guidelines for Opioid Treatment Programs acknowledge that legitimate medical practice for the treatment of addiction may include patients who engage in disruptive behaviors including dealing drugs and that they should be the subjects of "[c]linical interventions… aimed at retaining these patients in treatment."[iii] In addition, The ASAM Criteria, a nationally recognized guideline for the treatment of addiction, notes that patients who relapse while suffering from substance use disorder should not be discharged from treatment, but rather evaluated for a transfer to a different treatment regimen.[iv]

Furthermore, a clear and thoughtful delineation between the legitimate practice of medicine and the illegal distribution of drugs warranting law enforcement investigation is necessary if SAMHSA wants patients with substance use disorder to feel comfortable seeking medical treatment and clinicians to feel comfortable treating them.[v] Just recently, a study of physicians found that 13.8% of them cited their fear of the DEA intruding into their practice as a barrier to treating patients who had an addiction involving opioid use.[vi] Perhaps, even more importantly, we know that health care providers who treat addiction work with patients who have past or current legal problems, including drug dealing. Patients who participate in drug dealing often do so in order to maintain an active addiction. Hence, expanding the scope of "extremely serious crimes" as currently contemplated by the preamble, without the provision of any safe harbor language, and for the express purpose of increasing law enforcement access to confidential communications by patients, is inconsistent with encouraging a medical model framework for the treatment of the disease of addiction and may result in unintended consequences.

In short, the preamble to this NPRM could invite misguided DEA and other law enforcement raids or investigations that could cause abrupt and inappropriate discontinuation of addiction treatment services to a vulnerable patient population that has access to a deadly, illicit drug market, and it could further dissuade physicians and other health care providers from offering evidence-based treatments that are necessary to manage and end the opioid overdose crisis. Therefore, ASAM respectfully requests that SAMHSA further clarifies what constitutes an "extremely serious crime" in a way that does not materially alter the phrase's historical meaning, and, at a minimum, leaves it to independent courts to determine when drug-related crimes are sufficiently analogous to "extremely serious crimes" as set forth in §2.63(a)(2). Without SAMHSA's explicit and clear reassurances that authorities do not intend by this NPRM to obtain confidential communications for the purposes of criminalizing symptoms of addiction or clinical interventions aimed at retaining these patients in treatment, the language in this NPRM's preamble may exacerbate the addiction treatment workforce shortage and increase overdose deaths, particularly if coupled with any revision to §2.63(a)(2)'s rule text.

Again, ASAM is grateful for the opportunity to comment on this NPRM. ASAM will continue to advocate for the highest treatment standards and the most compassionate care for patients with addiction, and we look forward to collaborating with SAMHSA to refine and improve 42 CFR Part 2 to ensure our patients can easily access state-of-the-art treatment within our healthcare system. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Senior Director of Advocacy and Government Relations, at kcorredor@asam.org or at 301-547-4111.

Thank you,

Paul Earley, MD, DFASAM
President, American Society of Addiction Medicine

[i] In re August, 1993 Regular Grand Jury, 854 F. Supp. 1380, 1384-85 (SD. Ind. 1994)
[ii] Id. at 1385.
[iii] Substance Abuse and Mental Health Services Administration. (2015). *Federal Guidelines for Opioid Treatment Programs*. Retrieved from https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf.
[iv] Mee-Lee, D., Shulman, G., Fishman, M., Gastfriend, D., Miller, M., Provence, S. (2013). *The ASAM Criteria* (3rd ed). Chevy Chase, MD: ASAM Publications Department, 51.
[v] McCance-Katz, Ellinore F. (2019, April 29). Treating Opioid Use Disorder [SAMHSA blog post]. Retrieved from https://blog.samhsa.gov/2019/04/29/treating-opioid-use-disorder .
[vi] Andrilla, H., Coulthard, C., Larson, E. *Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder.* Ann Fam Med July/August 2017 15:359-362; doi:10.1370/afm.2099